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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,075	06/25/2004	Mari Tabuchi	1422-0634PUS1	5317
225/2	7590	03/24/2009	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH			BALL, JOHN C	
PO BOX 747			ART UNIT	PAPER NUMBER
FALLS CHURCH, VA 22040-0747			1795	
NOTIFICATION DATE		DELIVERY MODE		
03/24/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/500,075	Applicant(s) TABUCHI ET AL.
	Examiner J. CHRISTOPHER BALL	Art Unit 1795

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(o).

Status

- 1) Responsive to communication(s) filed on 16 January 2009.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,3,4 and 6-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,3,4 and 6-8 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-146/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Summary

1. This Office Action based on the Amendment after Final Action under 37 CFR 1.116 filed with the Office on January 16, 2009, regarding the TABUCHI et al. application.

2. Claims 1, 3, 4, and 6-8 are currently pending and have been fully considered.

Continued Examination Under 37 CFR 1.114

3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 16, 2009, has been entered.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 1 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over an article by GORDON et al. ("Protocol for Resolving Protein Mixtures in Capillary Zone Electrophoresis", ANALYTICAL CHEMISTRY, v63, n1, January 1, 1991, pp. 69-72).

Regarding claims 1 and 6-8, GORDON teaches preparation of a sample comprising proteins of interest in water (second sentence, first paragraph of "CZE Run Conditions", pg 70) and in a control experiment, protein in only water (fifth paragraph of Results & Discussion, p. 72), for electrophoretic protein separations (remainder of the first paragraph of "CZE Run Conditions", pg 70). Even though the protein in only water is not the preferred method of GORDON, the art does teach the limitation. The proteins separated from the mixture in GORDON (second paragraph of "CZE Run Conditions", pg 70) were not heat denatured in the stated protocol.

GORDON teaches the electrophoresis buffer used in the disclosed studies have pH values of either 9.6, 10.0, 10.2, or 11.0 (first paragraph of "CZE Run Conditions", pg 70).

GORDON does not teach that the electrophoresis buffer has a pH of 2.0 to 9.0.

However, it is well established that the pH of a buffer affects the charge of proteins, and thus the protein electrophoretic mobility. Therefore, in the Examiner's view, pH is a result effective variable in regards to the electrophoresis of proteins. As such, it would be obvious to one of ordinary skill in the art at the time of the invention to optimize the pH for the electrophoresis of any given protein, and, in doing so, it would be obvious to attempt electrophoresis of proteins in a buffer with a pH value between 2.0 and 9.0, among other values.

See MPEP 2144.05 (II)(B).

7. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over GORDON et al. ("Protocol for Resolving Protein Mixtures in Capillary Zone Electrophoresis", ANALYTICAL CHEMISTRY, v63, n1, January 1, 1991, pp. 69-72) as applied to claims 1 and 5-8 above, and further in view of TADAYONI-REBEK et al. (U.S. Patent Application Publication 2002/0155455 A1).

Regarding claims 3 and 4, GORDON teaches the limitations recited in claim 1 as outlined above.

GORDON does not disclose molecular weight markers subject to electrophoresis together with a protein.

However, TADAYONI-REBEK discloses high homogeneous molecular markers for electrophoresis, wherein is taught the use of marker molecules comprising a collection of two or more marker molecules (paragraph [0019]). TADAYONI-REBEK also teaches the addition of the marker molecule composition to a sample containing protein (paragraph [0022]), which would constitute the following a general protocol for an electrophoresis method.

At the time of the present invention, it would have been obvious to one of ordinary skill in the art to modify the protocol of GORDON with the utilization of molecular weight markers taught by TADAYONI-REBEK because doing so allows one to obtain highly homogeneous visible molecular markers that are compatible with commercially available separation techniques (TADAYONI-REBEK et al., last sentence of paragraph [0011]).

Additionally, the concentration of molecular weight markers would be recognized as a result effective variable. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to try various concentrations of the molecular weight markers in the electrophoresis process. This would include adjusting the concentration of a molecular weight marker below a comparable standard concentration, as recited in claim 3; or adjusting the concentration of a molecular weight marker to some level between 0.1 and 10 times the concentration of the protein being tested, as recited in claim 4.

Adjusting the concentration level of reagents, including molecular weight markers, would be obvious for one of ordinary skill in the art to attempt in an effort to optimize the electrophoresis separation. See MPEP 2144.05 (II)(B).

Response to Arguments

8. Applicant's arguments, see Remarks, p. 4, filed January 16, 2009, with respect to claim 6 have been fully considered and are persuasive. The objection of claim 6 has been withdrawn.
9. Applicant's arguments, see Remarks, p. 5-13, filed January 16, 2009, with respect to the rejection(s) of claim(s) 1, 3, 4, and 6-8 under 35 USC 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Examiner's new view of the prior art of record.
10. The applicant's arguments that the Examiner has not appropriately resolved the *Graham* factors, specifically:
 1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.

However, the Examiner points to the rejection of this Action and of previous Actions regarding the instant application that the scope and the content of the

prior art are in fact made explicit (e.g., "Gordon teaches. . ." or "TADAYONI-REBEK discloses. . .") and the ascertained differences between the prior art and the claims are also made explicit (e.g., "GORDON does not teach. . .").

A further in the *Graham* factor is "4. Considering objective evidence present in the application indicating obviousness or nonobviousness". As the claims currently stand, the methods claimed are taught by the prior art, GORDON et al., as GORDON contains all the limitations presented in the independent claims, even though the results of GORDON differ from the results disclosed in the instant specification. It is agreed by the Examiner that the results included in the applicants disclosure present an invention that has achieved unexpected results in that no protein absorption seems to be present and reproducibility of electropherograms is obtained by simply dissolving a protein in water and adding this resulting sample to an electrophoresis buffer without addition of common-to-art steps to avoid protein absorption. But, the claims are not drawn to these unexpected results, and it would be improper for the Examiner to import limitations from the specification into the claims. Such limitations in the claims would apparently make the claims novel and unobvious over the prior art of record, as pointed out the in the applicant's remarks (p. 8), GORDON's experiments without ethylene glycol result in non-reproducible electropherograms.

11. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. CHRISTOPHER BALL whose telephone number is (571)270-5119. The examiner can normally be reached on Monday through Thursday, 8:00 am to 5:00 pm (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JCB
AU 1795
03/18/2009

/Alex Noguerola/
Primary Examiner, Art Unit 1795
March 19, 2009